ORIGINAL ARTICLE

Porous High-Density Polyethylene Implants in Auricular Reconstruction

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Objective: To evaluate the ability of porous high-density polyethylene (Medpor) implants to tolerate exposure and support skin grafts when used to reconstruct defects in auricular cartilage in an animal model.

Design: Polyethylene implants placed in surgically created defects in auricular cartilage and covered with a skin flap were then exposed at either 4, 7, or 21 days after implantation. The exposed implants were then allowed to heal secondarily or received a skin graft 1 week later. The ability of polyethylene implants to tolerate exposure and support skin grafts was observed clinically and via histological study of the implantation sites.

Subjects: Nine adult New Zealand rabbits.

Results: Polyethylene implants demonstrated excellent ability to tolerate wound exposure as early as 4 days after implantation, with extrusion of 1 of the 36 implants placed. The degree of secondary wound healing increased as the interval from implantation to exposure increased from 4 to 21 days. Exposed polyethylene implants in all groups also supported all 18 skin grafts placed 1 week after exposure of the implant surface.

Conclusions: Polyethylene implants are well tolerated as replacements for native cartilage in auricular reconstruction. Polyethylene implants tolerated wound exposure as early as 4 days after implantation and demonstrated the ability to heal by secondary intention and support skin grafts. This is likely because of the extent of fibrovascular ingrowth from surrounding tissue, which allows the material to behave more like native tissue and less like a foreign body in this setting.

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THE ACCURATE reconstruction of congenital or posttraumatic auricular defects represents an ongoing challenge. Despite remarkable advances in surgical techniques and the handling of both native and artificial graft materials in the last 2 decades, acceptable aesthetic results remain difficult to achieve. The lack of a single preferred material and method for auricular reconstruction is evidenced by the variety of techniques and materials in use. Each technique has disadvantages that limit its use clinically. Soft tissue flaps lack structural support to maintain their size and shape over time. Autologous cartilage is well tolerated in head and neck reconstruction but demands a high level of expertise to accurately carve a realistic framework. There is also the added morbidity of a second operative site to supply the donor cartilage. Cartilage allografts spare the added morbidity of a donor site wound but undergo a variable amount of resorption over time, which can significantly alter the final outcome. Allografts also carry the potential risk of transmissable viral agents.

Because of the inherent shortcomings of cartilage, a number of synthetic materials have been used to substitute for the auricular framework. Biologically inert nonporous substances tend to induce an interface of a vascular capsule between the implant and the recipient tissues. Experience has revealed that infection in this setting is not well tolerated and leads to rapid implant extrusion. Investigations aimed at enhancing the biocompatibility of implant materials have focused largely on the changing nature of the implant-recipient interface. Omori et al[1] report success with silicone-Dacron mesh auricular frameworks, but their results have not been reproduced in other studies. More recently, porous high-density polyethylene

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EXHIBIT C

SUBJECTS AND METHODS

Nine adult, pathogen-free New Zealand rabbits were implanted with three 10×20-mm pieces of 1.5-mm-thick polyethylene and one 10×20-mm piece of 0.5-mm-thick solid silicone (Silastic sheeting model 500-5, Dow Corning Corp, Midland, Mich) to replace surgically excised portions of the native auricular cartilage. The animals were housed separately and given food and water ad libitum. All surgical procedures were performed under sterile operating conditions and with general anesthesia using sodium pentobarbital, 30 mg/kg intraperitoneally, following intramuscular administration of cephalothin sodium, 20 mg/kg.

After induction of the anesthesia, the rabbits were placed in a supine position to allow access to the ventral surface of each ear. They were then prepared with povidone iodine solution on all exposed auricular surfaces. An incision was made 0.5 cm from the lateral border of the ear extending from the base of each ear to a point 1.5 cm from the distal tip (**Figure 1**). The incision was carried down to the depth of the auricular cartilage. A skin-perichondrium flap was then elevated off the auricular cartilage to provide wide exposure for cartilage excision. Hemostasis was easily maintained throughout the procedure with a handheld electrocautery. Four 10×20-mm rectangular portions of auricular cartilage were then measured and outlined on each ear, taking care to keep 0.5-cm strips of intact cartilage between each excised area. The cartilage rectangles were sharply excised while avoiding damage to the underlying dorsal auricular blood vessels. Three of the resulting cartilage defects were filled with the 10×20-mm polyethylene implants while a single silicone implant was placed into the fourth defect. The skin-perichondrium flap was then sutured back into its original position with 5-0 nylon sutures at the lateral ear border and between each implant site.

The rabbits were then divided into 3 groups of 3 animals, each with implants placed in both ears, for a total of 6 ears per group. Animals in group 1 underwent exposure of their implants on day 4 following implantation. Group 2 animals underwent exposure on day 7 after implantation while group 3 animals underwent exposure on day 21 following implantation. A single polyethylene implant in each ear served as a histological control and was not exposed. The remaining 2 polyethylene implants and the silicone implant were exposed on day 4, 7, or 21 following implantation by the removal of a 10-mm circular portion of skin directly over the center of the implant. Seven days after exposure, 1 exposed polyethylene implant in each ear received a full-thickness skin graft harvested from the nape of the neck. The donor site was closed primarily. The skin grafts were sutured to the exposure sites with interrupted 5-0 nylon sutures after light débridement of any eschar overlying the implant surface. All animals were fitted with protective collars after implantation to prevent manipulation of the operative sites. The wounds were then monitored closely for signs of infection, seroma, or hematoma formation. The status of each ear was documented with photographs throughout the course of the study.

At the conclusion of the study the animals were killed in accordance with animal care and research guidelines at the Beth Israel Medical Center, New York, NY. The ears were removed and stored in formalin. Histological preparations were made with full-thickness cross-sectional specimens from each implant site. Hematoxylin-eosin staining was performed for light microscopic analysis. All histological processing was performed at the Department of Pathology, The New York Eye and Ear Infirmary, New York City. All procedures were reviewed and approved by the Committee on Scientific Affairs and the Committee of Animal Care and Use at the Beth Israel Medical Center. The animals were treated in accordance with procedures outlined by the National Institutes of Health, Bethesda, Md.

(Medpor Ultrathin Sheets, Porex Surgical Inc, College Park, Ga) and hydroxyapatite have generated interest because of the observation of fibrous and bony tissue ingrowth within the implant material, which improves tissue tolerance. Hydroxyapatite is difficult to manipulate because of its rigidity and has limited applications in certain anatomical regions, such as the auricle with its complex 3-dimensional shape. Porous high-density polyethylene possesses thermoplastic properties that allow ease of contouring without disturbing the macromolecular structure of the implant. The fibrous incorporation of the implant by recipient tissue yields increased vascularity and resistance to bacterial infection as well as improved stability over time.

Several studies[2-5] report rapid fibrovascular and bony ingrowth in these polyethylene implants used to reconstruct craniofacial defects. The use of these polyethylene frameworks to reconstruct auricles in burn patients is described by Wellisz.[6] In that study, 2 implants became exposed because of sloughing of the overlying fascial flap and skin. One of the implants received a skin graft directly while the other was allowed to close via secondary intention. Both cases yielded acceptable reconstructions.

Investigations into the biocompatibility of an expanded polytetrafluoroethylene patch (Gore-Tex Soft Tissue Patch, Gore & Assoc Inc, Flagstaff, Ariz) using a rabbit model were conducted by Maas et al.[7] Portions of the expanded polytetrafluoroethylene material were placed in subcutaneous pockets overlying the dorsum of the nose. Specimens of the skin, implant, and nasal bone were analyzed at intervals from 3 weeks to 12 months using standard histological and electron microscopic techniques. The results showed a trend in increasing tissue stability over time with minimal inflammatory response. The surrounding fibrous capsule remained thin and there was little or no evidence of alteration in implant structure. The expanded polytetrafluoroethylene material is similar to polyethylene but is manufactured in flat sheets and lacks the ability to maintain precise rigid shapes, which the molding process imparts to the polyethylene.

Recent animal studies by Sclafani et al[8] examine the effects of exposure and skin grafting on polyethylene implants using a rat model. Polyethylene implants were placed subcutaneously and later exposed to simulate skin sloughing. The wounds were then covered with a skin graft or allowed to heal secondarily. The results showed excellent tissue tolerance of the polyethylene implants in the

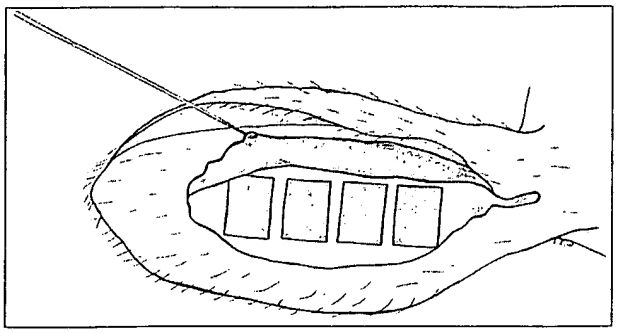

Figure 1. *Diagram of a rabbit ear showing placement of the skin-perichondrium flap and implant locations.*

Results of Implantation, Exposure, and Successful Skin Grafts for All Experimental Groups

Implant Type	Control	Exposed	Skin Grafts	Extruded
		Group 1		
Polyethylene	6	12	6	0
Silicone	2	4	0*	4
		Group 2		
Polyethylene	6	12	6	0
Silicone	2	4	0*	4
		Group 3		
Polyethylene	6	12	6	1
Silicone	2	4	0*	4

**In group 1, one attempted skin graft failed completely; in group 2, three attempted skin grafts failed completely; and in group 3, two attempted skin grafts failed completely.*

face of exposure and external contamination. Wound healing improved as the interval between implantation and exposure was lengthened from 2 to 14 days.

The current study was designed to more fully evaluate the nature of auricular wound healing in the setting of the exposed polyethylene implant material in a rabbit model. The implants were used to reconstruct surgically created defects in native auricular cartilage in the face of wound exposure with or without added skin graft coverage.

RESULTS

All animals survived the duration of the study and no implant sites became infected. A total of 54 of the polyethylene implants were placed with a single extrusion, while 12 of 18 silicone implants underwent extrusion (**Table**).

The polyethylene implants in group 1 (exposure on day 4) were all adherent to the surrounding tissues at the time of exposure, while the silicone implants remained mobile throughout the study. Seven days after exposure (day 11) these polyethylene implants were coated with a coagulum of blood, which bled when lightly abraded (**Figure 2**). Three of the 4 silicone implants extruded. Twenty days after exposure (day 24) all the exposed silicone implants had extruded with complete failure of the single attempted skin graft. Wounds with the exposed ungrafted polyethylene implants had undergone partial closure of the site. The exposed polyethylene implants

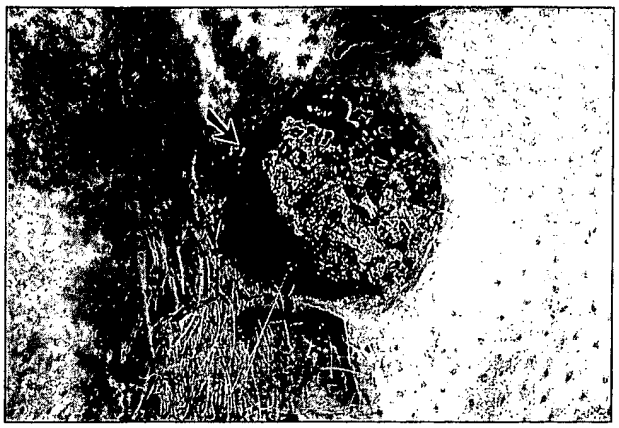

Figure 2. *Group 1 polyethylene implant exposure; note bleeding from implant surface (small arrow).*

were again covered with a coagulum of blood and bled when abraded. Seven of the polyethylene implants received skin grafts: 5 supported a 100% take of the graft while the remaining 2 supported a 50% take. The single silicone implant to have a skin graft placed demonstrated complete graft failure with subsequent extrusion of the implant.

All wound sites in group 2 (exposure on day 7) were well healed at both the polyethylene and silicone implant sites at the time of implant exposure. Seven days after exposure (day 14) 1 of the 4 silicone implants had extruded, while the other 3 remained fully exposed in the wounds. All 12 of the exposed polyethylene implants were covered with clotted blood and bled when abraded.

Three weeks after implant exposure (day 28) all the exposed silicone implants in group 2 had extruded and all 3 attempted skin grafts had failed. The 6 exposed polyethylene implants that did not receive skin grafts all showed complete wound healing and the polyethylene implants that received skin grafts all showed 100% graft survival.

The polyethylene implants in group 3 (exposure on day 21) were all noted to be surrounded by fibrous tissue that made them adherent to the overlying dermis. The silicone implants were encased in a dense layer of fibrous tissue that was not adherent to the implants. Seven days after implant exposure (day 28) 2 of the 4 silicone implants had extruded while the other 2 remained exposed in the wounds. Eleven of the 12 exposed polyethylene implants demonstrated more than 50% reepithelialization while the remaining implant showed minimal wound closure. The 6 polyethylene implants that underwent skin grafting were fully reexposed by sharp excision of the reepithelialized area over the original exposure site. All the implant sites bled when abraded.

Twenty-one days following exposure (day 42) all the exposed silicone implants had extruded and the 2 attempted skin grafts had failed completely in group 3. A single exposed, ungrafted polyethylene implant was noted to have sloughed 50% of the overlying skin coverage. Though it was partially extruded it remained adherent to the underlying deep wound surface within the carti-

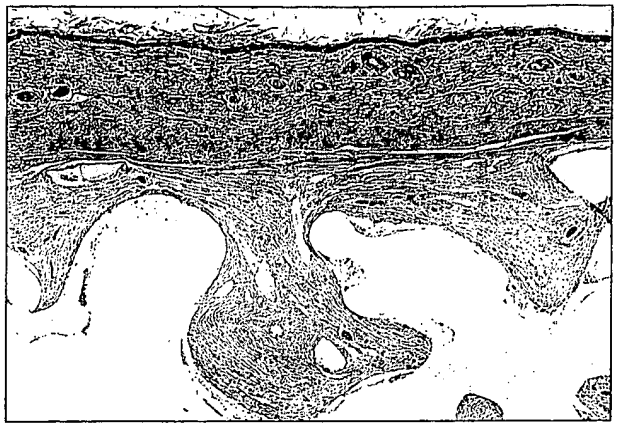

Figure 3. *Control polyethylene implant; note the surrounding fibrovascular tissue and the degree of tissue ingrowth within the substance of the implant (hematoxylin-eosin, original magnification ×4).*

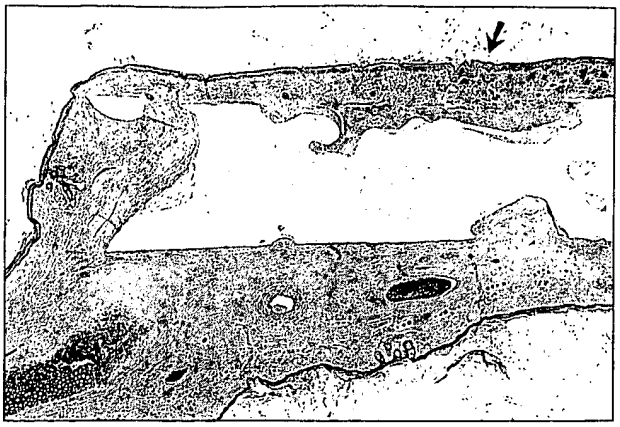

Figure 5. *Group 2 exposed polyethylene implant with full reepithelialization present 2 weeks following exposure. The arrow points to the exposure site (hematoxylin-eosin, original magnification ×2).*

Figure 4. *Group 1 polyethylene implant exposure site; note the epithelial tissue advancing over the exposed surface (arrow) (hematoxylin-eosin, original magnification ×4).*

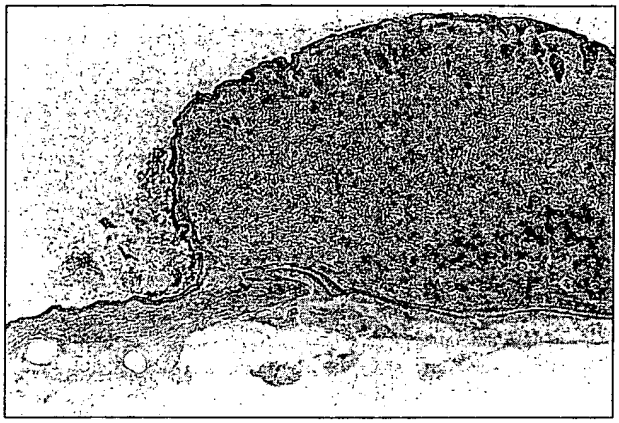

Figure 6. *Group 1 exposed polyethylene implant with a full-thickness skin graft in place over the exposure site (hematoxylin-eosin, original magnification ×4).*

lage defect. The remaining exposed, ungrafted polyethylene implants demonstrated complete reepithelialization over the exposure sites. All 6 of the exposed polyethylene implants that received skin grafts showed complete graft survival.

Findings of histological examinations of the unexposed polyethylene implants in all 3 groups demonstrated uniform fibrous tissue ingrowth by day 24. There was minimal inflammatory reaction present. The fibrovascular tissue surrounding the implants was noted to be only slightly thicker by day 42 (**Figure 3**).

The implants in group 1 (postexposure day 20, study day 24) were all incompletely reepithelialized and demonstrated a partial layer of necrotic material over the exposed implant surface. Epithelial migration was uniformly noted advancing from the periphery of the exposure sites (**Figure 4**).

The exposed implants in group 2 (postexposure day 21, study day 28) all demonstrated complete reepithelialization of the exposure sites (**Figure 5**). Evidence of fibrovascular tissue growth into the implant was present on all implant surfaces, including the exposed one. The fibrovascular tissue was noted to span the entire implant thickness in many areas. There was little evidence of inflammatory reaction around the implant margins or within the interior of the implants.

The implants in group 3 (postexposure day 21, study day 42) also showed complete reepithelialization over the exposed areas. The epithelium and subepithelial tissue layer was thicker than that seen in group 2. Numerous blood vessels were noted within the capsule surrounding each implant.

The polyethylene implants in group 1 supported skin grafts on their exposed surfaces (**Figure 6**). The grafts maintained their thickness during the study and fibrovascular tissue could be seen bridging the space between skin graft and implant surface. The implants in groups 2 and 3 also demonstrated preservation of graft thickness and maintenance of skin appendages with more extensive fibrovascular tissue ingrowth than seen in group 1 (**Figure 7**).

COMMENT

Alloplasts have been used for many years in facial reconstruction and augmentation with varying degrees of success. The ideal alloplastic material would show excellent host tissue tolerance, be easily manipulated to produce the required shape, show minimal recipient

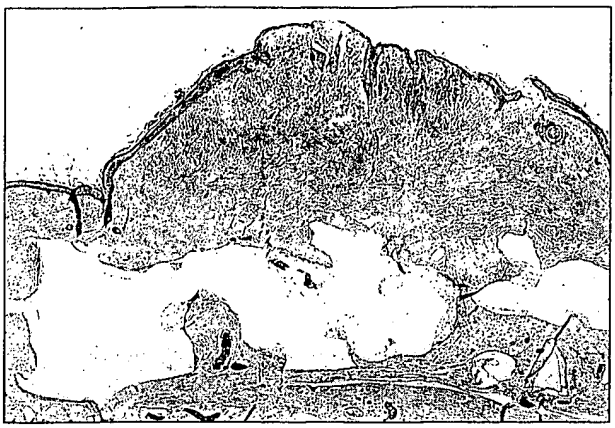

Figure 7. *Group 2 exposed polyethylene implant with a full-thickness skin graft in place over the exposure site; note preservation of skin appendages (hematoxylin-eosin, original magnification ×4).*

capsule formation, and demonstrate host tissue ingrowth, making it similar to native tissue. To date, the most significant drawback to the use of alloplasts has been the poor resistance to infection, with resultant implant extrusion. Results of work by Merritt et al[9] suggest that porous implants are more resistant to infection than nonporous implants if bacterial contamination happens after fibrous tissue ingrowth has occurred, but are at increased risk of extrusion if the bacteria are present prior to fibrous tissue ingrowth.

Solid silicone implants do not become integrated into recipient tissues and are thus prone to extrusion after infection or trauma. Omori et al[1] have reported frequent wound dehiscence when Dacron-covered silicone implants were used to reconstruct grades 1 and 2 microtias. They also noted a 9.5% rate of extrusion, occurring as long as 2 years after implantation. Porous polytef (Proplast, Vitek Inc, Houston, Tex) has been found to elicit a vigorous inflammatory response, resulting in degradation of the implant with resultant particle shedding and migration, despite the fact that it is a porous material with the potential for soft tissue ingrowth.[2,5,10,11] These drawbacks severely limit the use of this porous polytef in facial reconstruction. Polyamide mesh (Supramid, S. Jackson Inc, Alexandria, Va) allows soft tissue ingrowth but also causes a vigorous inflammatory response.[10]

Porous high-density polyethylene has been found to promote fibrous tissue ingrowth into its pores, which range in size from 100 to 250 μm. Tissue fluid circulates throughout the densely interconnected pores of the implant, which promotes rapid tissue ingrowth and vascularization.[12] The capsule formation is thin and flexible and causes a minimal inflammatory response. Shanbhag et al[13] implanted a small number of silicone and polyethylene disks into the auricular cartilage of baboons and found that 2 of 4 silicone implants extruded within 9 weeks of placement. The polyethylene implants became exposed but did not extrude in the same time interval. The exposures were preceded by eschar formation and subsequent skin sloughing. The exposures were thought to be caused by ischemic changes in the overlying skin, but the implants were retained because of fibrous tissue ingrowth and stabilization. Findings of histological examinations of their specimens revealed small blood vessels surrounding the polyethylene implants as well as ingrowth of collagen and blood vessels at the periphery of the implants. In contrast to the peripheral zone, the central region of each implant contained inflammatory cells with little collagen deposition.

Sclafani et al[8] report that polyethylene disks implanted under the dorsal skin of rats were completely invaded with fibrovascular tissue in 14 days. Partial exposure of the implants had minimal effect on this process. The capsule of fibrovascular tissue was found to remain thin and flexible with a minimal foreign body reaction, compared with the thick inflammatory capsule that was seen surrounding the solid silicone disks used for comparison.

The current study demonstrates that polyethylene implants used to reconstruct auricular cartilage defects undergo a similar rapid invasion by fibrovascular tissue. The unexposed polyethylene implants were uniformly invaded by granulation tissue, which traversed the full thickness of the implant. Minimal inflammatory reaction was noted when the implants were harvested anywhere from 24 to 42 days after implantation. The native cartilage adjacent to the implants did not show signs of inflammation or necrosis with either the unexposed or exposed polyethylene implants. The polyethylene implants were well tolerated in the setting of a full-thickness cartilage defect with coverage by a skin-perichondrium flap. These findings are supported by the fact that none of the 18 unexposed polyethylene implants extruded spontaneously. The polyethylene implants maintained a high degree of adhesion within the auricular implantation sites and behaved much like native auricular tissue in this experimental model.

It is encouraging that exposed polyethylene implants were well tolerated in reconstruction of the auricle. The implants in group 1 that were exposed early (day 4) did not extrude. The rate of wound closure and coverage by epithelial migration was slow and none of the 6 implants demonstrated total coverage 20 days after the exposures were performed. Group 1 implants were most remarkable in their ability to support skin grafts placed 7 days after exposure. The grafts all demonstrated a blood supply that originated both from the periphery of the wound and from the surface of the implant itself (Figure 6). The implants in groups 2 and 3, which were exposed 7 and 21 days, respectively, after implantation, all demonstrated full epithelial coverage at the end of the study. It is interesting to note that the single partially extruded polyethylene implant occurred in group 3, which had the longest interval between implantation and exposure. Improper handling of the implant and/or auricular tissue may be responsible for the extrusion in this case. Given this partial extrusion, it is encouraging to note the degree of fibrous tissue adhesion present between implant and recipient tissues, which might permit secondary skin grafting in the clinical setting. None of the experimental animals developed chondritis in this study, but given the severity of this form of infection it is doubtful that polyethylene implants or any other alloplast would be retained in the setting of severe cartilage necrosis. All the polyethylene implants in groups 2 and 3 that received skin grafts healed with total graft survival.

Silicone implants were uniformly extruded after exposure regardless of the time interval between implantation and exposure. All attempts at skin graft placement over exposed silicone implants resulted in graft failure. This finding supports the concept that the grafts were nourished by vascular ingrowth directly from the exposed polyethylene implant surface and not primarily from the peripheral skin edge and soft tissue, which were unable to support skin grafts placed on solid silicone implants.

The results of this study suggest that polyethylene implants tolerate auricular wound exposure far better than nonporous silicone implants. This is because of the specific porosity of the polyethylene implants, which promotes vigorous fibrovascular ingrowth. This ingrowth makes the implants far more stable when exposed and promotes better healing by either secondary intention or skin grafting. Similar porosity is also present in polytef implants, which might demonstrate similar behavior in this setting but lack the structural rigidity that polyethylene provides. Porous high-density polyethylene auricular framework implants may offer a reasonable addition to the current armamentarium of techniques available for use in this challenging area of reconstructive surgery.

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